





#19 Driv 1240

PTO/SB/08A (10-01)
Approved for use through 10/31/2002, OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO **Application Number** 09/663,600 INFORMATION DISCLOSURE September 15, 2000 Filing Date STATEMENT BY APPLICANT First Named Inventor DUMAS MILNE EDWARDS, et al. Art Unit 1646 (use as many sheets as necessary) Examiner Name Eileen B. O'Hara Attorney Docket Number G-031US03CIP Sheet

			U,S. PATE	ENT DOCUMENTS	
Examiner Initials		Document Number  Number- Kind Code <sup>2</sup> (if known		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
EIK	1	us-6,022,715	02-08-2000	Marenkova et al.	A11
		US-			
		US-			
		US-			
		US-			$\wedge$
		US-	×		
		US-			
		US-		ve v	2 5 0
		US-			0. 2
		US-			12001
		US-	·		5
		US-			7, 6
		US-			0 - 0
		us-			23
		US-	·		30
		US-			- O
		US·			
	<u> </u>	US-			
	<u> </u>	us-			A**
		us-			

		FORE	IGN PATENT D	OCUMENTS		
Examiner Initials	Cite No.1	Foreign Patent Document  Courty Code 3 - Number 4 - Kind Code 9 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	<b>T</b> 6
<i>27</i> 4	Α	WO 97/07198 - A2	02/27/1997	Genetics Institute Inc.	A11	
SIA	В	WO 98/45436 - A2	10/15/1998	Genetics Institute Inc.	A11	
<u> </u>	С	WO 99/06548 - A2 & A3	02/11/1999	Genset	A11	
EAC	٥	WO 99/25825 - A2	05/27/1999	Genset	A11	
514	E	WO 00/12708 - A2	03/09/2000	Genentech Inc.	A11	
EM	F	WO 00/18915 - A2	04/06/2000	Incyte Pharmaceuticals	A11	
ENA	G	WO 00/26360 - A1	05/11/2000	Adherex Technologies	A11	
	н	•				
L				·		

	<del></del>		
Examiner	En: B 011.	Date	1/23/12
Signature	Cilcan Fill forma	Considered	11/3/03

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

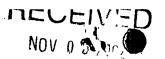
File Coss

\$11

+

<sup>&</sup>lt;sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.





TECH CEIVIER 1600/2900 PTO/SB/08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet of

	Complete If Known							
Ĺ	Application Number	09/663.600						
	Filing Date	September 15, 2000						
	First Named Inventor	DUMAS MILNE EDWARDS, et al.						
	Group Art Unit	1646						
	Examiner Name	Eileen B. O'Hara						
ľ	Attorney Docket Number	G-031US03CTP						

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue symposium, catalog, etc.), date, page(s), volume-issue	7			
EAR	j	FURUSE, et al.; "Claudin-1 and -2: Novel Integral Membrane Proteins Localizing at Tight Junctions with No Sequence Similarity to Occludin"; The Journal of Cell Biology, Vol. 141, No. 7, June 29, 1998, pp. 1539-1550; The Rockefeller University Press, 0021-9525/98/06/15391/12				
	к	FURUSE, et al.; "Manner of Interaction of Heterogeneous Claudin Species Within and Between Tight Junction Strands"; The Journal of Cell Biology, Vol. 147, No. 4, November 15, 1999, pp. 891-903; The Rockefeller University PRess, 0021-9525/99/11/891/13				
	ı	KATAHIRA, et al.; "Molecular Cloning and Functional Characterization of the Receptor for Clostridium perfringens Enterotoxin"; The Journal of Cell Biology, Vol. 136, No. 6, March 24, 1997, pp. 1239-1247; The Rockefeller University Press, 0021-9525/97/03/1239/9				
	м	KINUGASA, et al.; "Claudins Regulate the Intestinal Barrier inResponse to Immune Mediators"; Gastroenterology 2000; Vol. 118; pp. 1001-1011; The American Gastroenterological Association; 0016-5085/00				
	N	LIPPOLDT, et al.: "Organization of choroid plexus epithelial and endothelial cell tight junctions and regulations of claudin-1, -2 and -5 expression by protein kinase C"; Molecular Neuroscience, NeuroReport, Vol. 11, No. 7, pp. 1427-1431, May 15, 2000; Lippincott Williams & Wilkins, 0959-4965				
	0	LOCKHART, et al.; "Expression monitoring by hybridizationto high-density oligonucleotide arrays": Research Article; Nat Biotecnnol. 14(13):1675-80; Published Dec 1996; XP-002074420				
	Р	TASHIRO, et al.: "Signal Sequence Trap: A Cloning Strategy for Secreted Proteins and Type 1 Membrane Proteins"; Science, Vol. 261, July 30, 1993; pp.600-603; XP-000673204	_			
	a	YOKOYAMA-KOBAYASHI, et al.; "A signal sequence detection system using secreted protease activity as an indicator"; Gene, Vol. 163 (1995), pp. 193-196; Elsevier Science B.V.; SSDI 0378-1119(95)00322-3				
	R	Accession No. AAG17984; Claudin-2, Homo Sapiens, Database: Genbank; GU, J.R., et al., submitted August 1999; "Novel human cDNA clone with function of inhibiting cancer cell growth"; Unpublished	-			
	s	Accession No. AAC27079; Claudin-2, Mus musculus; Database: Genbank; FURUSE, et al.; submitted June 15, 1998; "Claudin-1 and -2: Novel Integral Membrane Proteins Localizing at Tight Junctions with No Sequence Similarity to Occludin"; J. Cell Biol. 141 (7), 1539-1550 (1998)				
V	т	Accession No. T03538; Bento Soares Homo sapiens cDNA clone IB43; Database: EMBL; SIKELA, J.M.; submitted September 21, 1992	+			

Examiner	5,	Q -N1	Date	1/22/12
Signature	_ ( sleer	D'O Name	Considered	1/23/03

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.





PTO/SB/08B (10-01)

LUS. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

(use as many sheets as necessary) of Sheet

Complete if Known					
Application Number	09/663.600				
Filing Date	September 15, 2000				
First Named Inventor	DUMAS MILNE EDWARDS, et a				
Group Art Unit	1646				
Examiner Name	Eileen B. O'Hara				
Attorney Docket Number	G-031US03CIP				

OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the ltem (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>		
EAR EAR	U	Accession No. AA057573; Homo sapiens cDNA clone IMAGE:381523; Database: EMBL; WILSON; submitted September 6, 1996			
EAR	٧	Accession No N57409; Homo sapiens cDNA clone (MAGE:258726; Database: EMBL; WILSON; submitted February 22, 1996			
·	w				
	×				
	Y				
	z				
	AA				
	АВ				

Examiner	ران کی کی	Data	11 1
	Cileer D-0 Nan	Date	1/24/02
Signature	Clary 12 - (110)	Considered	1/2/103

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Complete if Known Substitute for form 1449B/PTO **Application Number** 09/663,600 INFORMATION DISCLOSURE Filing Date September 15, 2000 STATEMENT BY APPLICANT First Named Inventor J.-B. Dumas Milne Edwards **Group Art Unit** 1646 (use as many sheets as necessary) **Examiner Name** Eileen B. O'Hara G-031US03CIP **Attorney Docket Number** Sheet of

		NON PATENT LITERATURE DOCUMENTS	
E≭aminer In∎tials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
EA	R1	INTRONA, M. and GOLAY, J., "How can oncogenic transcription factors cause cancer: a critical review of the myb story" <i>Leukemia</i> (1999), 13:1301-1306; Stockton Press	
EA EA	R2	WARD, A.C. et al., "Regulation of granulopiesis by transcription factors and cytokine signals" Leukemia (2000), 14:973-990; Macmillan Publishers, Ltd.	
EA	R3	STEWART, G., "The membrane defect in hereditary stomatocytosis", Baillière's Clinical Haematology (1993), 6(2):371-99; Baillière's Tindall	
	R4		
	R5		
	R6		
,	R7		
	R8		
	R9		
	R10		
	R11		
	R12		
	R13		

Signature   Considered   Cons
--

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, te (13

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Control number.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Control number.

Substitute fo	r form 1449A	VPTO		Complete if Known		
INEOD	MATIO	W DICC	LOSURE	Application Number	09/663.600	
				Filing Date	September 15, 2000	
STATE	MENT	BY AP	PLICANT	First Named Inventor	DUMAS MILNE EDWARDS, et al.	
(1)				Art Unit_	1646	
(use as many sheets as necessary)				Examiner Name	Eileen B. O'Hara	
Sheet	1	of	3	Attorney Docket Number	G-031USO3CIP	

			U.S. PATE	ENT DOCUMENTS	
Examiner Ci Initials No		Document Number  Number - Kind Code <sup>2</sup> (if known	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
	1_	us.6,022,715	02-08-2000	Marenkova et al.	Figures Appear All
	<u> </u>	US-			
		US-			
		US-	···		
		US-			
		US-			
		US-	$\triangle$		
		US-	<del> </del>		
		US-		$\sim$ $\sim$ $\sim$	
		us-			
		US-			
		us-		1/-	
		US-			
<del></del>		US-	/ \		
		US-			
		US·		V /	
		US-			
		us-			
		US-			
		lus.	1	T	

FOREIGN PATENT DOCUMENTS								
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	No. 1	Courty 20063 -Number* - Kind Code* :# known:				Té		
	Α_	WO 97/07198 - A2	02/27/1997	Genetics Institute Inc.	A11			
مه	. В	WO 98/45436 - A2	10/15/1998	Genetics institute Inc.	A11			
	С	WO 99/06548 - A2 & A3	02/11/1999	Genset	A11			
	D	WO 99/25825 - A2	05/27/1999	Genset	A11	_		
	E	WO 00/12708 - A2	03/09/2000	Genentech inc.	All			
	F	WO 00/18915 - A2	04/06/2000	Incvte Pharmaceuticals	A11			
	G	WO 00/26360 - A1	05/11/2000	Adherex Technologies	A11			
	н				<u> </u>			
	-1					_		
				T				

1 Examiner	Dave
Signature	Date
Signature	Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.cov">www.uspto.cov</a> or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 5 Applicant is to place a check mark nere if English language Translation is attached. English language Translation is attached.

PTO/SB/08B (10-01)
Approved for use through 10/31/2002, OM9 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute f	or form 1449B/PTC	)		Complete if Known		
			OL COURT	Application Number	09/663.600	
ווארטר	KMAHON	<b>DIS</b>	CLOSURE	Filing Date	September 15, 2000	
STAT	EMENTE	Α Υ	PPI ICANT	First Named Inventor	DUMAS MILNE EDWARDS, et al.	
STATEMENT BY APPLICANT				Group Art Unit	1646	
(use as many sheets as necessary)				Examiner Name	Eileen B. O'Hara	
Sheet 3		of	3	Attorney Docket Number	G-031US03CIP	

Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, senal, symposium, catalog, etc.), date, page(s), volume-issue	7
	C	Accession No. AA057573; Homo sapiens cDNA clone IMAGE:381523; Database: EMBL; WILSON; submitted September 6, 1996	
	>	Accession No N57409; Homo sapiens cDNA clone IMAGE:258726; Database: EMBL; WILSON; submitted February 22, 1996	
	w		
	х		
	٧		
	z		
	AÀ		
	AB		
			-

Examiner Date Signature

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the Individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE				Complete if Known		
				Application Number	09/663.600	
INFO	KMAHON	DIS	CLOSURE	Filing Date	September 15, 2000	
STAT	EMENTE	Y A	PPLICANT	First Named Inventor	DUMAS MILNE EDWARDS, et al.	
יראיטן		, , ,	LIOAII	Group Art Unit	1646	
(use as many sheets as necessary)				Examiner Name	Eileen B. O'Hara	
Sheet	2 of 3		3	Attorney Docket Number	G-031US03CIP	

Examiner Initials	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue	7
	٦	FURUSE, et al.; "Claudin-1 and -2: Novel Integral Membrane Proteins Localizing at Tight Junctions with No Sequence Similarity to Occiudin"; The Journal of Cell Biology, Vol. 141, No. 7, June 29, 1998, pp. 1539-1550; The Rockefeller University Press, 3021-9525/98/06/15391/12	
	к	FURUSE, et al.: "Manner of Interaction of Heterogeneous Claudin Species Within and Between Tight Junction Strands"; The Journal of Cell Biology, Vol. 147, No. 4, November 15, 1999, pp. 891-903; The Rockefeller University PRess. 0021-9525/99/11/891/13	
	L	KATAHIRA, et al.; "Molecular Cloning and Functional Characterization of the Recestor for Clostricium perfringens Enterotoxin"; The Journal of Cell Biology, Vol. 136, No. 6, March 24, 1997, pp. 1239-1247; The Reckefeller University Press, 0021-9525/97/03/1239/9	
	м	KINUGASA, et al.: "Clauding Regulate the intestinal Barrier inResponse to Immune Mediators"; Gastroenterology 2000; Vol. 118; pp. 1001-101; The American Gastroenterological Association; 0015-5085/00	
	N	LiPPOLDT, et al.: "Organization of choroid piexus port eliat and endothelial cell tight junctions and regulations of claudin-1, -2 and -5 expression by protein kinase 77; Morecular Neuroscience, NeuroReport, Vol. 11, No. 7, pp. 1427-1431, May 15, 2000; Lippincott Williams & Wilkins, 09594965	
	0	LOCKHART, et al.: "Expression monitoring by hybridization to high-density oligonucleotide arrays": Research Article: Nat Biotechnol 14(13):1675-30. Published Dec 1996: XP-302074420	
	P	TASHIRO, et al.: "Signal Sequence Trad: A Cloning Grategy for Secreted Proteins and Type 1 Memorane Proteins": Science, Vol. 234 Listy 30, 1993; pp.500-503; XP-000673204	
	G	YOKOYAMA-KOBAYASHI, et al.: "A signal sequence detection system using secreted protease activity as an indicator": Gene. Vol. 183 (1995), pp. 193-198: Elsevier Science B.V.; SSDI 0373-1119(95)00322-3	
	R	Accession No. AAG17984; Claudin-2, Homo Saciens, Database: Genbank; GU, J.R., et al.; submitted August 1999; "Novel human cDNA clone with function of inhibiting cancer cell growth"; Unpublished	
	s	Accession No. AAC27079; Claudin-2, Mus musculus; Database: Genbank; FURUSE, et al.; submitted June 15, 1998; "Claudin-1 and -2; Novel Integral Memorane Proteins Localizing at Tight Junctions with No Sequence Similarity to Occludin"; J. Cell Biol. 141 (7), 1539-1550 (1998)	
	T	Accession No. T03538; Bento Soares Homo sapiens cDNA clone IB43; Database: EMBL; SIKELA, J.M.; submitted September 21, 1992	

Examiner	 Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial If reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DC NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.